

PTO-1390 (Rev. 07-2005)
Approved for use through 03/31/2007. OMB 0651-0021
U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL LETTER TO THE UNITED STATES

ATTORNEY'S DOCKET NUMBER 64651(45579)

| DESIGNATED/ELECTED OFFICE (DO/EO/US) | U.S. APALICATION NO (F Known) see 87 (FR 1.5) | | | | | |
|--|--|--|--|--|--|--|
| CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE | PRIORITY DATE CLAIMED | | | | | |
| PCT/DK2004/000482 5 July 2004 | 4 July 2003 | | | | | |
| TITLE OF INVENTION PARATHYROID HORMONE (PTH) CONTAINING PHARMACEUTICAL COMPOSITIONS FOR ORAL USE | | | | | | |
| APPLICANT(S) FOR DO/EO/US Lisbeth Bønløkke et al. | | | | | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/ | US) the following items and other information: | | | | | |
| 1. x This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. | | | | | | |
| 2. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. | | | | | | |
| 3. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. | | | | | | |
| 4. x The US has been elected (Article 31). | | | | | | |
| 5. x A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) | | | | | | |
| a. is attached hereto (required only if not communicated by the International Bureau). | | | | | | |
| b. x has been communicated by the International Bureau. | | | | | | |
| c is not required, as the application was filed in the United States Received | , , | | | | | |
| 6. An English language translation of the International Application as filed (35 | 5 U.S.C. 371(c)(2)). | | | | | |
| a. is attached hereto. | | | | | | |
| b. has been previously submitted under 35 U.S.C. 154(d)(4). | | | | | | |
| 7. X Amendments to the claims of the International Application under PCT Artic | de 19 (35 U.S.C. 3/1(c)(3)) | | | | | |
| a. are attached hereto (required only if not communicated by the International Bureau). | | | | | | |
| b. have been communicated by the International Bureau. | | | | | | |
| c. have not been made; however, the time limit for making such amendments has NOT expired. | | | | | | |
| d. x have not been made and will not be made. | | | | | | |
| 8. An English language translation of the amendments to the claims under Po | CT Article 19 (35 U.S.C. 371(c)(3)). | | | | | |
| 9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). | | | | | | |
| 10. An English language translation of the annexes of the International Prelimi Article 36 (35 U.S.C. 371(c)(5)). | nary Examination Report under PCT | | | | | |
| Items 11 to 20 below concern document(s) or information included: | | | | | | |
| 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. | | | | | | |
| 12. An assignment document for recording. A separate cover sheet in complia | ance with 37 CFR 3.28 and 3.31 is included. | | | | | |
| 13. X A preliminary amendment. | | | | | | |
| 14. x An Application Data Sheet under 37 CFR 1.76. | | | | | | |
| 15. A substitute specification. | | | | | | |
| 16. A power of attorney and/or change of address letter. | | | | | | |
| 17. A computer-readable form of the sequence listing in accordance with PC | CT Rule 13ter.2 and 37 CFR 1.821 – 1.825. | | | | | |
| 18. A second copy of the published International Application under 35 U.S.C | C. 154(d)(4). | | | | | |
| 19. A second copy of the English language translation of the international ap | oplication under 35 U.S.C. 154(d)(4). | | | | | |
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IAP20 ROC'D PUT/PTO 22 DEC 2005

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| U.S. APPLICATIO | I.S. APPLICATION NO. (IJIKNOVIII, 68 37 GFR 5) INTERNATIONAL APPLICATION NO. PCT/DK2004/000482 | | | ATTORNEY'S DOCKET NUMBER 64651(45579) | | | | |
|--|--|--------------------|---|--|----------|---------------------|---------------|--|
| 20. X Other items or information: Return Receipt Postcard, Copy of published PCT Application No. WO 2005/002549 A1, copy of PCT Forms PCT/RO/101, PCT/IB/304, PCT/IPEA/401, PCT/IPEA/416, PCT/ISA/210 | | | | | | | | |
| The foll | owing fees have | e been submitte | | | CA | LCULATION | S PTO USEONLY | |
| _ | • | | | \$300 | \$ | 300.0 | | |
| 21. x Basic national fee (37 CFR 1.492(a)) | | | | | \$ | 200.0 | 0 | |
| 23. X Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) | | | | \$ | 400.0 | 0 | | |
| | TOTAL OF 21, 22 | 2 and 23 = | | | \$ | 900.0 | 0 | |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | | | | |
| Total Sheets | Extra Sheets | | additional 50 or fraction up to a whole number) | RATE | | | | |
| 75 -100= | /50 = | | | x \$250.00 | \$ | | | |
| Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | | \$ | 130.0 | 0 | | | |
| CLAIMS | NUM | MBER FILED | NUMBER EXTRA | RATE | | | | |
| Total clair | ms 4 | 5 - 20 = | 25 | x 50.00 | | 1,250.0 | 0 | |
| Independent | claims | 3 - 3 = | | x | <u> </u> | 0.0 | 0 | |
| MULTIPLE DEP | ENDENT CLAIM(S | 6) (if applicable) | | + | <u> </u> | | | |
| | | | TOTAL OF A | BOVE CALCULATIONS = | \$ | 2,280.0 | 0 | |
| Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | | | ļ | | | | |
| SUBTOTAL = | | | \$ | 2,280.0 | 0 | | | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | | \$ | | | | | |
| TOTAL NATIONAL FEE | | | \$ | | 2,280.00 | | | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + | | | | | | | | |
| TOTAL FEES ENCLOSED = | | | | | \$ | | 2,280.00 | |
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|--|---|--|--|--|
| 1 | ve fees And 20 NC 1 PCT/PTO 22 DEC 200 punt of \$ 2,280.00 to cover the above fees. | | | |
| Please charge my Deposit Account No. 04-1105 in the amount of this sheet is enclosed. | to cover the above lees. | | | |
| The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 04-1105 . A duplicate copy of this sheet is enclosed. | | | | |
| Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038 | | | | |
| :: Where an appropriate time limit under 37 CFR 1.495 has not been an granted to restore the International Application to pending statu | | | | |
| | 1/1/1/2 | | | |
| D ALL CORRESPONDENCE TO: | SIENATURE | | | |
| er F. Corless WARDS ANGELL PALMER & DODGE LLP | | | | |
| Box 55874 on, Massachusetts 02205) 439-4444 | Peter F. Corless NAME | | | |
| OMER NUMBER: 21874 | 33,860 REGISTRATION NUMBER | | | |
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IAP20 RSC'd PCT/PTO 22 DEC 2005

Application No. (if known): Not Yet Assigned

Attorney Docket No.: 64651(45579)

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EV754866755US in an envelope addressed to:

MS PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

| on | December 22, 2005 | | |
|----|-------------------|--|--|
| | Date | | |

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|------------------------------------|----------------------------|
| Sign | ature |
| Susar | Dillon |
| Typed or printed name of | person signing Certificate |
| | (617) 439-4444 |
| Registration Number, if applicable | Telephone Number |

Note:

Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Application Data Sheet (3 pages)

Declaration for Utility or Design Patent Application

Return Receipt Postcard, Copy of published PCT Application No. WO 2005/002549 A1, copy of PCT Forms PCT/RO/101, PCT/IB/304,

PCT/IPEA/401, PCT/IPEA/416, PCT/ISA/210

Preliminary Amendment

Transmittal Letter to the United States Designated-Elected Office

Charge \$2,410.00 to deposit account 04-1105